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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
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| 10/083,199 | 02/26/2002 | Hai Trieu | 4002-2950/PC464.00 | 5676 | |
| 52196 | 7590 07/19/2006 | | EXAM | EXAMINER | |
| KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS. IN 46204-2709 | | | PHILOGENE, PEDRO | | |
| | | | ART UNIT | PAPER NUMBER | |
| | • | | 3733 | | |
| | | | | DATE MAILED: 07/19/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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| Office Action Summary | | Application No. | Applicant(s) |
| | | 10/083,199 | TRIEU ET AL. |
| | | Examiner | Art Unit |
| | | Pedro Philogene | 3733 |
| Period fo | The MAILING DATE of this communication apport Reply | ears on the cover sheet with th | e correspondence address |
| WHIC - External exter | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATI 36(a). In no event, however, may a reply burill apply and will expire SIX (6) MONTHS for cause the application to become ABANDO | ION. e timely filed rom the mailing date of this communication. DNED (35 U.S.C. § 133). |
| Status | | | |
| 2a)⊠ | Since this application is in condition for allowar | action is non-final. | |
| | closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, | 453 O.G. 213. |
| Dispositi | ion of Claims | | |
| 5)□ 6)⊠ 7)□ | Claim(s) <u>1-21,23-31,33-38 and 78-99</u> is/are per 4a) Of the above claim(s) <u>15-21,23-31,34,36,37</u> Claim(s) is/are allowed. Claim(s) <u>1-14,33,35,38 and 78-88,90-99</u> is/are Claim(s) is/are objected to. Claim(s) are subject to restriction and/or | and 89 is/are withdrawn from rejected. | consideration. |
| Applicati | ion Papers | | |
| 10) | The specification is objected to by the Examiner The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the o Replacement drawing sheet(s) including the correcti The oath or declaration is objected to by the Ex | epted or b) objected to by the drawing(s) be held in abeyance. Sign is required if the drawing(s) is | See 37 CFR 1.85(a). objected to. See 37 CFR 1.121(d). |
| Priority u | under 35 U.S.C. § 119 | | |
| a) | Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau See the attached detailed Office action for a list of | s have been received. s have been received in Applic ity documents have been rece I (PCT Rule 17.2(a)). | eation No eived in this National Stage |
| 2) Notice (3) Inform | et(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) cer No(s)/Mail Date | 4) Interview Summ Paper No(s)/Mai 5) Notice of Inform 6) Other: | |

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 33,35,38,78-88,90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant fails to disclose a body having a length extending "extradiscally" to a second vertebral body. Although applicant is claiming "extradiscally" nowhere in the specification is an explanation of the word "extradiscally" is given. Since applicant is introducing the word "extradiscally" to overcome a rejection and since the word "extradiscally" was never presented in the original claims and specification, it is considered as new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-14, 33,35,38,78-88,90-99 are rejected under 35 U.S.C. 102(e) as being anticipated by Carl et al (6,607,530).

With respect to claims 1, 78, 91, Carl et al disclose a spine stabilization system comprising an implant (160) having first and second ends, at least a portion of one of the first and second end s structured for positioning in use in a channel formed in a fist vertebral body; and at least one anchor (400) sized to be embedded within the first vertebral body without protruding from the first vertebral body; as set forth in column 10, lines 18-25, column 13, lines 64-67, at least one of a first end and second end of the implant is angled relative to the portion for positioning into the first vertebral body in the tunnel; as best seen in FIGS.6a-b; including means (the curvature in FIGS.6,a-b) for conforming to a first vertebral body. The at least one anchor and the one of the first and second ends being configured to engage one another in the tunnel with the means for conforming in contact with the first vertebral body; as best seen in FIGS.6,a-b. The implant including a body having a length and structure to extend from the tunnel "extradiscally" to a second vertebral body or to conform to the first vertebral body outside the tunnel; as set forth in column 13, lines 14-17, also as best seen in FIGS.10.

With respect to claims 2-14, 33, 35, 38,79-88, 90,92-99, Carl et al discloses all the limitations, as set forth in column 10, lines 18-25, column 11, lines 26-67, column 13, lines 8-17, lines 64-67, column 14, lines 35-48.

Response to Amendment

Applicant's arguments filed 5/8/06 have been fully considered but they are not persuasive. Applicant stated that Carl et al did not teach an implant including a body

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having a length and structure to extend from the tunnel "extradiscally" to a second vertebral body. First, applicant's attention is directed to the 112 rejection above. Second, as understood, Carl et al disclose all the limitations, as claimed by applicant. For example, in column 13, lines 14-17, and FIG.10, Carl et al disclose that "the implant can be arranged so as to include a biting or expansion element(s) that can be driven out in a lateral direction so as to engage the bony structure of the vertebrae", therefore, the imp[lant conforms to the vertebral body outside the tunnel. As to applicant's argument concerning claims 2-14, 33,35,38, that "wherein at least one anchor extends along and threadingly engages said one of said first and second ends of said, the screw (400) of Carl et al threadingly engages the ends of the implants; as set forth in column 13, lines 10-13. As to the end portion of the implant being relatively angled to the other one, applicant's attention is directed to FIG.10. As to the manner in which the anchor extends in relation to the implant. Applicant is reminded that the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. As to claim 97, applicant's attention is directed to FIG.10.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene July 11, 2006

PEDRO PHILOGENE PRIMARY EXAMINER